

REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated October 30, 2007 and Advisory Action dated April 24, 2008.

Applicants have above amended the Specification at each of pages 9 and 40 to reference the ATCC deposition of sHIgM22 (LYM22) antibody myeloma. Applicants submit herewith a copy of the receipt and confirmation of the ATCC deposit as ATCC Patent Designation PTA-8671. Applicants respectfully submit that this amendment provides clarification and particular necessary reference to the ATCC deposit and accession number and does not introduce new matter and respectfully request entry and acceptance thereof.

Claims 42-43, 73 and 91-95 are pending in the application as presently amended. Claims 73 and 91-93 have been deemed allowable by the Examiner, as noted in the Office Action dated October 30, 2007 and confirmed in the Advisory Action dated April 24, 2008. Claims 42 and 43 have been amended, and new claims 94 and 95 have been added, in order to more particularly point out and distinctly claim that which Applicants regard as the invention. New claims 94 and 95 refer particularly to antibody sHIgM22 (LYM22) as deposited as ATCC Accession No. PTA-8671 and pharmaceutical compositions thereof. Support for the amended claims and new claims can be found generally through Applicants' Specification. In particular, support for new claims 94 and 95 and the ATCC deposition is provided herewith and in the Specification particularly as above amended, including at pages 9, line 16-17, and page 40, lines 7-8.

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

***Claim Rejections - 35 USC § 112, First Paragraph***

The Examiner has maintained his rejection of claims 42-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the

specification, while being enabling for antibodies comprising a heavy chain variable sequence comprising the heavy chain variable region of SEQ ID NO: 7 and a light chain variable region sequence comprising the light chain variable region of SEQ ID NO: 9, does not reasonably provide enablement for monoclonal antibody sHGM22 (LYM22). While the Examiner agrees that it is well within the skill of the artisan to make many of the fragments and monomers recited in claim 42, he notes that both claims 42 and 43 specifically recite LYM22 antibody, which cannot be made in the absence of undue experimentation. The Examiner maintains his determination that in order for the skilled artisan to make the LYM22 antibody recited in claims 42 and 43, the artisan must have access to the hybridoma that produces the antibodies.

Applicants respectfully disagree. Claims 42 and 43 refer to and recite antibodies having a heavy chain comprising the heavy chain variable region sequence of SEQ ID NO: 7 and a light chain comprising the light chain variable region sequence of SEQ ID NO: 9, IgM monomers or Fab, Fab', F(ab')<sub>2</sub> and Fv fragments thereof, and as such the claims are directed to antibodies or pharmaceutical compositions comprising particular and specific heavy and/or light chain sequences. It would clearly be possible for one of skill in the art to make the claimed antibody or composition in the absence of the hybridoma or myeloma that produces it. Further, Applicants have above amended each of claims 42 and 43 to delete the descriptive recitation "mAb sHIgM22 (LYM 22)" and refer to "antibody". To the extent that the language of claims 42 and 43 has and continues to refer to particular sequences (SEQ ID NO: 7 and 9, for instance), Applicants assert and underscore that this amendment is merely a clarity amendment and does not result in any change in scope or intent of the claims. The artisan could generate antibodies with the claimed characteristics by manipulating the given heavy and light chain variable region sequences, including for instance using art recognized methods of generating recombinant or hybrid antibodies.

Applicants acknowledge that the availability of the isolated sHIgM22 (Lym22) antibody hybridoma would be helpful to the skilled artisan to make and/or test the antibodies of claims 42 and 43, it is not necessitated by the claims or required for enablement of instant claims 42 and 43, particularly in as much as these claims refer to "antibody". Applicants have, however, deposited the sHIgM22 (Lym22) hybridoma, under the terms of the Budapest Treaty, with the

US Serial No.  
10/010,729

PATENT  
1199-1-005CIP2

ATCC and provide herewith a copy of the receipt and confirmation of the ATCC deposit as ATCC Patent Designation PTA-8671. The undersigned, as agent of record, hereby states that the ATCC deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. Applicants have now added new claims 94 and 95, which are specifically directed to the sHlgM22 (LYM22) monoclonal antibody and fragments, monomers thereof and refer particularly to the ATCC deposited antibody. Applicants respectfully assert that claims 42 and 43, as well as new claims 94 and 95, fully comply with 35 U.S.C. 112, first paragraph and the enablement requirement.

In view of the foregoing remarks, Applicants submit that the Examiner's rejections under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

#### CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,  
KLAUBER & JACKSON, LLC

  
Christine E. Dietzel, Ph.D.  
Agent for Applicant(s)  
Registration No. 37,309

KLAUBER & JACKSON  
411 Hackensack Avenue  
Hackensack NJ 07601  
Tel: (201) 487-5800